REMARKS

This amendment and reply is in response to the Office Action dated July 2, 2007. Applicant has amended claims 1, 8, 39-49, 53, 54, 60 and 61. Claims 62-64 are new. No new matter is added. In amending the claims, Applicant does not concede that the claims as originally presented or previously amended are unpatentable over the references cited in the Office Action and reserves the right to pursue the previously presented claims in one or more continued applications. Claims 1-64 are presented for examination. In view of the foregoing amendment and following remarks, Applicant requests entry of the claim amendments and reconsideration and withdrawal of the rejections.

Claim Objections

The Office action objected to claims 1, 8 and 60-61 for several informalities. Applicant has amended those claims in accordance with the Examiner's suggestions and respectfully requests withdrawal of the objections.

Rejections Under 35 U.S.C. § 112 Rejections, 2nd Paragraph

Claims 17, 21, 22 and 60 were rejected as indefinite. In particular, the Examiner alleges that the language of claims 17, 21 , 22 and 60 is unclear. Applicant respectfully disagrees and submits that, in light of the specification, the referenced claim language is clear to one of ordinary skill in the art. Indeed, the fact that claim language may not be precise does not automatically render the claim language indefinite under 35 U.S.C. § 112, second paragraph. "Rather, acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." (MPEP § 2173.05(b)). Accordingly, even though claims 17, 21, 22 and 60 do not recite a specific numerical value or range of values for radiopacity or MRI visibility, it is clear from the specification that one of ordinary skill in the art would easily understand what is claimed.

For example, in regards to pending claims 17, 21 and 60, page 9, lines 1-21 of the specification disclose that it is possible to select a material that enhances MRI imaging without

degrading fluoroscopic imaging. In particular, the specification discloses that an MRI enhancement material can be chosen to have a radiopacity of about 0.9 less than the radiopacity of 316L stainless steel, as determined by the American Society for Testing and Materials (ASTM) F640. The ASTM is an international standards developing organization that develops and publishes technical standards for a wide range of materials, products, systems, and services. Accordingly, the specification clearly points out and discloses a reference that would be familiar to one of ordinary skill in the art and which could be used to obtain a generally accepted range of values for the radiopacity of steel.

Similarly, claim 22, which recites an MRI visibility equal or greater than "about 280 mg/ml gadodiamine in 5000 ml blood" would also be clear to one of ordinary skill in the art, in view of the specification. For example, the specification discloses that "[i]mage visibility can be determined by comparison to an MRI contrast agent such as Omniscan (Gadodiamine, Nycomed)." (Page 8 lines 6-22). Omniscan contains 287 mg/ml Gadodiamine and produces a clear bright contrast when used in 20ml injection bolus for an adult (5000 ml blood). (Page 8 lines 6-22). As such, the specification clearly points out and discloses a reference that would be familiar to one of ordinary skill in the art and which could be used to obtain a generally accepted level of MRI visibility.

Rejections Under 35 U.S.C. § 102

Independent claim 1 is currently amended to recite a medical device that includes a biocompatible body and an attachable marker band secured circumferentially to an outer surface of the biocompatible body. The marker includes a fluoroscopic imaging enhancement material and an magnetic resonance imaging (MRI) enhancement material, in which the fluoroscopic imaging enhancement material and MRI enhancement material are in separate concentric layers that are non-circumferentially contiguous. Similarly, claim 39 recites a marking system for marking a region of a medical device that includes a marker band which is circumferentially attachable to an outer surface of the medical device. The marker band includes a fluoroscopic imaging enhancement material and an MRI enhancement material in respectively concentric first

and second layers, which are non-circumferentially contiguous. Likewise, claim 54 recites a method of attaching a marker band to a medical device which includes positioning the marker band at a location along the medical device and circumferentially securing the marker at that location. The marker includes a fluoroscopic imaging enhancement material and a MRI enhancing material in respectively concentric first and second layers which are non-circumferentially contiguous.

Support for these features can be found in the example shown in FIG. 2A of the present application. In that example, a "C-shaped" marker band 15 includes a first imaging layer 30 that includes a radiopaque layer visible under fluoroscopy and a second MRI visibility enhancement layer 32, in which the layers 30 and 32 are positioned concentrically to each other. As shown in FIGS. 1A and 1B, the marker band 15 can be positioned and secured along medical devices such as a catheter body 6 (*see* pg. 6, lines 12-27) to enable visibility of the medical device under fluoroscopic and magnetic resonance imaging. The non-circumferentially contiguous "C-shape" of the marker band layers prevents electrical currents from looping the marker band. Accordingly, in some implementations, RF artifacts in MRI examinations are reduced.

In contrast, none of the cited references, disclose the subject matter of the pending claims, as amended.

Claims 1-3 and 54 are rejected under 35 U.S.C 102(b) as being anticipated by U.S. Patent No. 6,272,370 (Gilles). The Gilles patent discloses an MR visible and/or X-ray visible drug delivery device that includes a linearly arranged array of radio-opaque and MR-visible distal markers 6 that are identifiable in an MR image and by X-rays (see FIGS. 1-2; col. 25, lines 39-53). Although the Gillies et al. patent discloses markers 6, it fails to disclose the use of fluoroscopic imaging enhancement material and MRI enhancement material in "separate concentric layers" which are "non-circumferentially contiguous" as recited by pending claims 1, 54. Claims 2 and 3 are dependent on claim 1 and should be allowable for at least the same reasons. Applicants request withdrawal of the rejections.

Claims 7, 9, 10, 12-14, 29, 38-41, 43-44, 47, 48, 51 and 52 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. US 2005/0124976

(Devens). The Devens reference discloses a co-extruded medical tube that includes a first layer and second layer of different compositions bonded to the first layer (see para. 6; FIGS. 2A, 8B). The co-extruded medical tube can be used as a medical balloon, a guide wire, a vascular graft, shunt, or a variety of catheters in which the layers of the catheter include markers for fluoroscopic, ultrasound and/or magnetic resonance detection (see para. 58-62). Although the Devens reference discloses layers having markers for fluoroscopic and magnetic resonance detection, neither those layers nor the devices within which they are located correspond to "attachable" marker bands that are secured to an outer surface of a medical device or biocompatible body as recited in pending independent claims 1and 39. Instead, the layers containing the markers are co-extruded with and integrated as part of the medical device. Accordingly, one of ordinary skill in the art would have no reason to attach the layers to the outer surface of a medical device or biocompatible body as they already are integrated within a medical device. Moreover, even if the layers did correspond to attachable markers, which is incorrect, there is no disclosure as to how one of ordinary skill in the art would be able to secure the layers to the outer surface of a medical device or biocompatible body.

In addition, the Devens reference fails to disclose that the layers are "non-circumferentially contiguous" as also recited by pending claims 1 and 39. Instead, FIG. 2A clearly shows layers 24, 26 and 28 as contiguous tubular layers.

For at least these reasons independent claims 1 and 39 should be allowable. Claims 7, 9, 10, 12-14, 29 and 38 are dependent on claim 1 and should be allowable for at least the same reasons as claim 1. Claims 40, 41, 43, 44, 47, 48, 51 and 52 are dependent on claim 39 and should be allowable for at least the same reasons as claim 39. Applicants request withdrawal of the rejections.

Rejections Under 35 U.S.C. § 103

Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Gilles in view of U.S. Patent Application Publication No. 2007/0093142 (MacDonald). Claim 8 is dependent on claim 1 which recites a medical device that includes a biocompatible body and an attachable

marker band secured circumferentially to an outer surface of the biocompatible body. The marker includes a fluoroscopic imaging enhancement material and an magnetic resonance imaging (MRI) enhancement material, in which the fluoroscopic imaging enhancement material and MRI enhancement material are in separate concentric layers that are non-circumferentially contiguous. Claim 8 further requires a marker having multiple layers, the multiple layers having a thickness of about 0.005 inch or less.

As discussed above Gilles discloses an MR visible and/or X-ray visible drug delivery device that includes a linearly arranged array of radio-opaque and MR-visible distal markers 6 that are identifiable in an MR image and by X-rays (see FIGS. 1-2; col. 25, lines 39-53). Although the Gillies et al. patent discloses markers 6, it fails to disclose the use of fluoroscopic imaging enhancement material and MRI enhancement material in "separate concentric layers" which are "non-circumferentially contiguous" as recited by pending claims 1. Nor does Gilles disclose the claimed marker having multiple layers, the multiple layers having a thickness of about 0.005 inch or less, as required by Claim 8.

MacDonald does not overcome this deficiency. The MacDonald reference discloses an implantable medical device that includes a filter circuit for filtering out magnetic resonance imaging induced signals (see FIGS. 50-53). The device also includes electrically conductive and circumferentially contiguous coatings 480, 495, 505 and 520 that have low magnetic susceptibility for minimizing interaction with MRI induced magnetic fields (see para. 175). However, the MacDonald et al. reference fails to disclose the features missing from the Gillies patent reference. As such applicants request withdrawal of the rejection.

Claim 60 is rejected under 35 U.S.C. § 103(a) over Gilles in view of U.S. Patent No. 6,334,871 (Dor). Claim 60 is dependent on claim 54, which recites a method of attaching a marker band to a medical device which includes positioning the marker band at a location along the medical device and circumferentially securing the marker at that location. The marker includes a fluoroscopic imaging enhancement material and a MRI enhancing material in respectively concentric first and second layers which are non-circumferentially contiguous. Claim 60 further requires a radiopacity less than stainless steel at the location where the marker

is secured on the medical device. As described above, Gilles does not disclose the use of fluoroscopic imaging enhancement material and MRI enhancement material in "separate concentric layers" which are "non-circumferentially contiguous" as recited by claims 54 and 60.

Dor does not overcome this deficiency. The Dor patent discloses stents 1 which include radiopaque rivet markers 3 that are inserted through holes or openings 2 in the edges or ends of the stents (see col. 2, lines 15-19; col. 3, lines 6-12). The Dor et al. patent fails to disclose that the stent markers 3 are secured "circumferentially" to the outer surface of the stents or that the markers 3 include fluoroscopic imaging enhancement material and MRI enhancement material in "separate concentric and non-circumferentially contiguous layers" as recited by claims 54 and 60. As such Applicants request withdrawal of the rejection.

Claims 11, 15-37, 42, 45, 46, 49, 50, and 53 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. US 2005/0124976 (Devens) alone or in view of several tertiary references. Specifically, claims 16, 20, 29-34, 46, and 53 are rejected over Devens. Claims 15 and 35 are rejected over Devens in view of U.S. Patent No. 6,884,234 (Aita). Claims 17-19, 21 and 22 are rejected over Devens in view of U.S. Patent No. 6,334,871 (Dor). Claims 23, 24, 36, 37 and 42 are rejected over Devens in view of U.S. Patent Application Publication No. US 2005/0131522 (Stinson). Claims 25-28 are rejected over Devons in view of U.S. Patent Application Publication No. US 2006/0111646 (Gellman). Claims 11, 49 and 50 are rejected over Devons in view of U.S. Patent Application Publication No. US 2005/0215885 (Lee). And claim 45 is rejected over Devens in view of U.S. Patent No. 6,026,316 (Karcharczyk).

Applicants respectfully traverse these claim rejections because the reference relied on by the Examiner, Devons, may not preclude patentability of the claimed subject matter. Devons and the current application had a common assignee at the time the claimed invention was made. Indeed, 35 U.S.C. § 103(c)(1) states:

> Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at

> the time the claimed invention was made, owned by the same person....

The current application was assigned from the inventors to Scimed Life Systems, Inc., on March 3, 2004 and recorded in the USPTO on June 10th, 2004 at Reel No. 014716, Frame No. 0109. At the time the claimed invention was made, Devens was also assigned to Scimed Life Systems, Inc., by assignment from the inventors executed on February 23, 2004 and recorded in the USPTO on May 6th, 2004 at Reel No. 015294, Frame No. 0261. As such, Devens may not be used as invalidating prior art under § 103. Applicants request the rejections be withdrawn.

Claims 4-6, 55-59 and 61 are rejected under 35 U.S.C. § 103(a) as unpatentable over Gilles in view of U.S. Patent Application Publication No. US 2004/0193140 (Griffin). Applicants respectfully traverse these claim rejections because the reference relied on by the Examiner, Griffin, may not preclude patentability of the claimed subject matter. Griffin and the current application had a common assignee at the time the claimed invention was made. Like Devons above, Griffin was also assigned to Scimed Life Systems, Inc.—recorded in the USPTO on March 27, 2003 at Frame No. 013916 and Reel No. 0233. Applicants request the rejections be withdrawn.

Conclusion

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

The fee for the Petition for Extension of Time is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply any other charges or credits to Deposit Account No. 06-1050..

Respectfully submitted,

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